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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,320	02/15/2001	D. Wade Walke	LEX-0137-USA	3185

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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,320

Applicant(s)

WALKE ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other:

DETAILED ACTION

Status of the Application

Claims 4-5 are pending.

Applicant's election with traverse of Group II, claim 4 drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 4, cancellation of claims 1-3 and 6-10, and a request to correct inventorship in Paper No. 10, filed on 3/5/2002 are acknowledged.

Applicant's traverse is on the ground(s) that the nucleic acids described in SEQ ID NO: 1, 3, and 5 and the corresponding polypeptides (SEQ ID NO: 2, 4, and 6) are all encoded by a common genetic locus and are therefore not independent. Applicants argue that Groups I, II, and III should be combined since they are drawn to nucleic acids which share a common nexus of invention. Further, Applicants argue that at least Group II and III (claims 4 and 5) should be rejoined because the polynucleotide of SEQ ID NO: 3 contains SEQ ID NO: 5 in its entirety and that SEQ ID NO: 3 contains 98 nucleotides more than SEQ ID NO: 5.

Applicant's arguments have been fully considered but are not deemed persuasive to overcome the restriction requirement. Applicant's arguments with regards to Group I are moot in view of the cancellation of the claims of this group. With regards to Groups II and III, Applicants assert that the only difference between the polynucleotides of SEQ ID NO: 3 and 5 and the corresponding polypeptides of SEQ ID NO: 4 and 6, is that SEQ ID NO: 3 comprises all of SEQ ID NO: 5 and that SEQ ID NO: 5 is missing only 98 nucleotides. It is noted that the specification does not disclose the relationship between SEQ ID NO: 3 and 5 as asserted by Applicants in Paper No. 10. Upon alignment of SEQ ID NO: 3 and 5, it was found that SEQ ID NO: 3 is not 98 nucleotides longer than SEQ ID NO: 5 but rather 621 nucleotides longer.

Art Unit: 1652

Similarly, an alignment of SEQ ID NO: 4 and 6 revealed that SEQ ID NO: 4 is 207 amino acids long. Therefore, one cannot conclude that the function of the polypeptide of SEQ ID NO: 6 is necessarily identical to that of SEQ ID NO: 4 or that SEQ ID NO: 6 is an obvious fragment of SEQ ID NO: 4. In addition, no disclosure has been provided of what the function of the additional 207 amino acids is or how the polypeptides of SEQ ID NO: 4 and 6 are related. Each polynucleotide and polypeptide disclosed in the instant invention comprise a different structure and function, therefore they are patentably distinct inventions. Furthermore, the search and examination of Groups I-VI would impose an undue burden on the Office since the search is not co-extensive.

The requirement is deemed proper and therefore is made FINAL.

Claim 5 is withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

1. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/183,582 filed on 2/18/2000 and provisional application No. 60/184,014 filed on 2/22/200.

Inventorship

2. In view of the papers filed on 3/5/2002, the inventorship in this nonprovisional application has been changed by the deletion of Yi Hu and Boris Nepomnichy.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 4 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

Applicants assert that the polypeptides encoded by the polynucleotides of the instant application share structural similarity to animal kinases (page 1, lines 33-35) and that these kinases include, but are not limited to, cell division control protein kinases, serine/threonine protein kinases, guanylate kinases (page 2, lines 1-5). Therefore, Applicants assert, the polypeptides encoded by the polynucleotides of the instant application encode a novel kinase family having homologs and orthologs across a range of phyla and species.

However, based upon Applicant's disclosure, the claimed invention does not meet the utility requirement for the following reasons. First, one cannot determine which type of kinase is being encoded by the polynucleotide of the instant invention (SEQ ID NO: 3). Kinases belong to a large and diverse family with different specificities and substrates. Therefore, one of skill in the art cannot determine the actual function and consequently, the use of the protein (SEQ ID NO: 4) encoded by the polynucleotide (SEQ ID NO: 3) of the instant invention. In addition, neither Applicant's disclosure, nor the state of the art at the time the invention was made provides guidance as to what the function of the polypeptide of SEQ ID NO: 4 is, its specificity or its substrate. No working examples have been provided either. No disclosure of critical

Art Unit: 1652

structural elements which would indicate the type of kinase being encoded by the polynucleotide (SEQ ID NO: 3) of the instant application is provided.

Applicant's asserted utility for the polypeptide of SEQ ID NO: 4 (kinase), particularly in view of a lack of knowledge as to the type of kinase, specificity and substrate, constitutes a utility that requires further research to identify or reasonably confirm a "real world" context of use. See e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). This type of utility is not considered a "substantial utility". An assay that detects the presence of an agent that has a stated correlation to a predisposition to the onset of a specific disease condition would be considered a "substantial utility" in the context of identifying potential candidates for preventive measures. Here the polynucleotide and corresponding polypeptide are suitable only for additional research. Thus, for the reasons set forth, the claimed polynucleotide does not have a real-world use and hence lack utility for the reasons set forth above.

4. Claim 4 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

5. No claim is in condition for allowance.

6. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

Art Unit: 1652

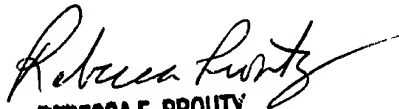
7. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 16, 2002


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600